

IN THE UNITED STATES DISTRICT COURT  
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

IN RE: DIET DRUGS (PHENTERMINE/ FENFLURAMINE/DEXFENFLURAMINE) PRODUCTS LIABILITY LITIGATION	)	MDL NO. 1203
_____	)	
THIS DOCUMENT RELATES TO:	)	
SHEILA BROWN, et al.	)	
v.	)	CIVIL ACTION NO. 99-20593
AMERICAN HOME PRODUCTS CORPORATION	)	2:16 MD 1203

MEMORANDUM IN SUPPORT OF SEPARATE PRETRIAL ORDER NO. 8989

Bartle, J.

January 8, 2013

Nicholas Napora ("Mr. Napora" or "claimant"), a class member under the Diet Drug Nationwide Class Action Settlement Agreement ("Settlement Agreement") with Wyeth,<sup>1</sup> seeks benefits from the AHP Settlement Trust ("Trust"). Based on the record developed in the show cause process, we must determine whether claimant has demonstrated a reasonable medical basis to support his claim for Matrix Compensation Benefits ("Matrix Benefits").<sup>2</sup>

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1. Prior to March 11, 2002, Wyeth was known as American Home Products Corporation.

2. Matrix Benefits are paid according to two benefit matrices (Matrix "A" and Matrix "B"), which generally classify claimants for compensation purposes based upon the severity of their medical conditions, their ages when they are diagnosed, and the presence of other medical conditions that also may have caused or contributed to a claimant's valvular heart disease ("VHD"). See Settlement Agreement §§ IV.B.2.b. & IV.B.2.d.(1)-(2). Matrix A-1 describes the compensation available to Diet Drug Recipients with serious VHD who took the drugs for 61 days or longer and who did (continued...)

To seek Matrix Benefits, a claimant must first submit a completed Green Form to the Trust. The Green Form consists of three parts. The claimant or the claimant's representative completes Part I of the Green Form. Part II is completed by the claimant's attesting physician, who must answer a series of questions concerning the claimant's medical condition that correlate to the Matrix criteria set forth in the Settlement Agreement. Finally, claimant's attorney must complete Part III if claimant is represented.

In April, 2003, claimant submitted a completed Green Form to the Trust signed by his attesting physician, David M. Gonzalez, M.D. Based on an echocardiogram dated November 9, 2002, Dr. Gonzalez attested in Part II of Mr. Napora's Green Form that he suffered from moderate mitral regurgitation and an abnormal left atrial dimension. Based on such findings claimant would be entitled to Matrix A-1, Level II benefits in the amount of \$590,261.<sup>3</sup>

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2. (...continued)

not have any of the alternative causes of VHD that made the B matrices applicable. In contrast, Matrix B-1 outlines the compensation available to Diet Drug Recipients with serious VHD who were registered as having only mild mitral regurgitation by the close of the Screening Period or who took the drugs for 60 days or less or who had factors that would make it difficult for them to prove that their VHD was caused solely by the use of these Diet Drugs.

3. Under the Settlement Agreement, a claimant is entitled to Level II benefits for damage to the mitral valve if he or she is diagnosed with moderate or severe mitral regurgitation and one of five complicating factors delineated in the Settlement Agreement.

(continued...)

In the report of claimant's echocardiogram, Dr. Gonzalez stated that Mr. Napora had moderate mitral regurgitation, measured at 25%. Under the definition set forth in the Settlement Agreement, moderate or greater mitral regurgitation is present where the Regurgitant Jet Area ("RJA") in any apical view is equal to or greater than 20% of the Left Atrial Area ("LAA"). See Settlement Agreement § I.22.

In July, 2005, the Trust forwarded the claim for review by Vincent L. Sorrell, M.D., F.A.C.P., F.A.C.C., one of its auditing cardiologists. In audit, Dr. Sorrell concluded that there was no reasonable medical basis for the attesting physician's finding that claimant had moderate mitral regurgitation. In support of this conclusion, Dr. Sorrell explained, "[Mitral regurgitation] was absent. The color flow traced in the [left atrium] was backflow and not [mitral regurgitation]."

Based on the auditing cardiologist's finding that claimant did not have moderate mitral regurgitation, the Trust issued a post-audit determination denying Mr. Napora's claim. Pursuant to the Rules for the Audit of Matrix Compensation Claims

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3. (...continued)

See Settlement Agreement § IV.B.2.c.(2)(b). As the Trust does not contest the attesting physician's finding of an abnormal left atrial dimension, which is one of the complicating factors needed to qualify for a Level II claim, the only issue is claimant's level of mitral regurgitation.

("Audit Rules"), claimant contested this adverse determination.<sup>4</sup> In contest, claimant submitted a letter from Dr. Gonzalez regarding his February 23, 2003 echocardiogram along with two additional echocardiogram reports from Abdou El-Hendy, M.D. and Juan J. Vazquez Bauza, M.D., F.A.C.C. In his letter, Dr. Gonzalez stated that he had "reviewed the echocardiogram and found ... [m]ild to borderline moderate mitral insufficiency." Dr. El-Hendy stated that the claimant's November 9, 2002 echocardiogram demonstrated a "structurally normal mitral valve with mild regurgitation." Mr. Napora also submitted the report of Dr. Bauza based on his review of an echocardiogram dated August 9, 2004. Dr. Bauza noted that this echocardiogram demonstrated "[t]race of mitral regurg[itation]." In addition, Mr. Napora submitted various articles regarding Diet Drugs, valvular heart disease, the relationship between Diet Drugs and valvular heart disease, and the Settlement Agreement.<sup>5</sup>

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4. Claims placed into audit on or before December 1, 2002 are governed by the Policies and Procedures for Audit and Disposition of Matrix Compensation Claims in Audit, as approved in Pretrial Order ("PTO") No. 2457 (May 31, 2002). Claims placed into audit after December 1, 2002 are governed by the Audit Rules, as approved in PTO No. 2807 (Mar. 26, 2003). There is no dispute that the Audit Rules contained in PTO No. 2807 apply to Mr. Napora's claim.

5. Mr. Napora also referenced a number of motions he has filed with the court. For example, Mr. Napora filed two motions for relief from the Seventh Amendment, asserting that the Seventh Amendment was unfair and seeking the production of documents and information from the Seventh Amendment Liaison Committee, the Trust, Class Counsel, and Wyeth in connection with the negotiation and implementation of the Seventh Amendment.

(continued...)

Mr. Napora also argued that he was prejudiced because his lawyers terminated their representation when he opted out of the Seventh Amendment. Finally, Mr. Napora asserted that there was a reasonable medical basis for his claim because (1) his physicians found a number of medical conditions that Dr. Sorrell did not, and (2) Wyeth offered to resolve his claim by allowing him to receive Category Two benefits under the Seventh Amendment.<sup>6</sup>

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5. (...continued)

Mr. Napora also filed a motion for "7<sup>th</sup> Amendment Monthly Reports" and information on how actual claims are being reviewed. We approved the Seventh Amendment to the Settlement Agreement as non-collusive, fair, adequate, and reasonable in all respects after holding a fairness hearing and providing more than 600,000 potentially affected class members and their attorneys notice and an opportunity to lodge objections. PTO No. 4567 at 1-2 (Mar. 15, 2005). As these motions do not raise any meritorious challenge, we will deny each of them.

6. Mr. Napora also contended that he was unable to respond effectively because the Trust did not provide him sufficient information about the audit. Mr. Napora filed a motion to request disclosure of all auditors' pass rates. As the pass rate of the Trust's auditors has no bearing on the validity of Mr. Napora's claim, we will deny this motion. Mr. Napora also filed a motion to cease all activity at the Trust and for a full investigation into the Trust's auditing activities and appointment of a special investigator to investigate the accusations of intentional material representation that have been made by the Trust, the lack of prosecution by the Trust, and settling of fraudulent claims. As part of our continuing jurisdiction over the Settlement Agreement, we have resolved a number of issues involving purportedly illegitimate claims and the Trust's handling of the audit process. Further, there is no basis for the relief Mr. Napora seeks. In any event, the issues raised by their motion are more appropriately resolved by way of specific objections in the context of individual claims for benefits. Accordingly, we will deny this motion. In addition, Mr. Napora filed a motion seeking disclosure of "the information that was used by the Trust and the Trust auditor in coming to their 'observation'" so that he may file a rebuttal to the

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The Trust then issued a final post-audit determination, again denying Mr. Napora's claim. Claimant disputed this final determination and requested that the claim proceed to the show cause process established in the Settlement Agreement. See Settlement Agreement § VI.E.7.; PTO No. 2807; Audit Rule 18(c). The Trust then applied to the court for issuance of an Order to show cause why Mr. Napora's claim should be paid. On May 6, 2008, we issued an Order to show cause and referred the matter to the Special Master for further proceedings. See PTO No. 7814 (May 6, 2008).

Once the matter was referred to the Special Master, the Trust submitted its statement of the case and supporting documentation. Claimant then served a response upon the Special Master. Under the Audit Rules, it is within the Special Master's discretion to appoint a Technical Advisor<sup>7</sup> to review claims after

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6. (...continued)  
 opinion of the auditing cardiologist; and a motion for an order directing the Trust to turn over all evidence, conclusions, expert's notes, opinions, lawyer conversations, and all other material the Trust used and/or possesses in issuing its Final Post-Audit Determination in this claim. Even if a basis existed for these requests for additional information, given our disposition of this claim, in which Mr. Napora's own submissions confirm the existence of less than moderate mitral regurgitation in his November 9, 2002 echocardiogram, any documents Mr. Napora might obtain would have no bearing on the outcome of this proceeding. Accordingly, we also will deny these motions.

7. A "[Technical] [A]dvisor's role is to act as a sounding board for the judge-helping the jurist to educate himself in the jargon and theory disclosed by the testimony and to think through the critical technical problems." Reilly v. United States, 863 F.2d 149, 158 (1st Cir. 1988). In a case such as this, where there  
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the Trust and claimant have had the opportunity to develop the Show Cause Record. See Audit Rule 30. The Special Master assigned a Technical Advisor, Gary J. Vigilante, M.D., F.A.C.C., to review the documents submitted by the Trust and claimant and to prepare a report for the court. The Show Cause Record and Technical Advisor Report are now before the court for final determination. See id. Rule 35.

The issue presented for resolution of this claim is whether claimant has met his burden in proving that there is a reasonable medical basis for the attesting physician's finding that he had moderate mitral regurgitation. See id. Rule 24. Ultimately, if we determine that there is no reasonable medical basis for the answer in claimant's Green Form that is at issue, we must affirm the Trust's final determination and may grant such other relief as deemed appropriate. See id. Rule 38(a). If, on the other hand, we determine that there is a reasonable medical basis for the answer, we must enter an Order directing the Trust to pay the claim in accordance with the Settlement Agreement. See id. Rule 38(b).

In support of his claim, Mr. Napora repeats the arguments he made in contest. In addition, he submits the Supplemental Declaration of Dean Karalis, M.D., F.A.C.C., who was

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7. (...continued)  
are conflicting expert opinions, a court may seek the assistance of the Technical Advisor to reconcile such opinions. The use of a Technical Advisor to "reconcil[e] the testimony of at least two outstanding experts who take opposite positions" is proper. Id.

retained by Class Counsel to review Mr. Napora's echocardiogram. Although Dr. Karalis finds that Mr. Napora's November 9, 2002 echocardiogram demonstrates at most mild mitral regurgitation, Mr. Napora argues that such finding undermines Dr. Sorrell's conclusion that Mr. Napora does not have mitral regurgitation. Mr. Napora also submitted correspondence between him and the Trust and between him and the Special Master's office. Finally, he contends, without any support, that Dr. Bauza's finding of trace mitral regurgitation based on Mr. Napora's August 9, 2004 echocardiogram can be explained because discontinuation of Diet Drug use can alter the level of mitral regurgitation and because mitral valve prolapse can skew the measurement of the mitral valve.

The Technical Advisor, Dr. Vigilante, reviewed claimant's echocardiogram and concluded that there was no reasonable medical basis for the attesting physician's finding of moderate mitral regurgitation. Specifically, Dr. Vigilante determined that:

Evaluation of the mitral apparatus demonstrated that this was a normal valve with normal leaflet thickness and good excursion.... Visually, no mitral regurgitation was seen in the parasternal long-axis view. Trace mitral regurgitation was suggested in the apical views. I digitized the cardiac cycles in the apical four chamber and two chamber views in which the mitral regurgitant jet was noted. I digitally traced and calculated the RJA and LAA. I was able to accurately planimeter the RJA in the mid portion of systole in spite of increased color gain. In the apical four chamber view, the largest representative RJA

was 1.0 cm<sup>2</sup>. The LAA in the apical four chamber view was 21.4 cm<sup>2</sup>. Therefore, the largest representative RJA/LAA ratio was less than 5%, consistent with trace mitral regurgitation. In fact, the RJA was within 1 cm of the mitral annulus. In the apical two chamber view, I was also able to accurately planimeter the RJA in spite of increased color gain. The RJA was less than 1.0 cm<sup>2</sup>. The LAA in the apical two chamber view was 23.1 cm<sup>2</sup>. Therefore, the largest representative RJA/LAA ratio was much less than 5% and diagnostic of trace mitral regurgitation. The RJA/LAA ratio never came close to approaching 20%. There was one sonographer-determined RJA noted in an off axis apical four chamber view. This supposed RJA was measured at 4.89 cm<sup>2</sup>. This was not seen in real time and was diagnostic of backflow. In addition, the sonographer determined the LAA at 19.3 cm<sup>2</sup>. This did not completely take into account the lateral portion of the left atrium. The inaccurate sonographer-determined RJA and LAA values are the same ones noted on the sonographer worksheet.

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In response to Question 1, there is no reasonable medical basis for the Attesting Physician's answer to Green Form Question C.3.a. That is, the echocardiogram of November 9, 2002 demonstrated trace mitral regurgitation with comments as above. The RJA/LAA ratio did not come close to approaching 20%. An echocardiographer could not reasonably conclude that moderate mitral regurgitation was present on this study even taking into account inter-reader variability.

In response to the Technical Advisor report, Mr. Napora states that he is not able to refute the Technical Advisor's findings because he has not been able to speak with his former attorney, whom Mr. Napora says is responsible for obtaining his echocardiogram. Claimant also states that he did not ask for his

echocardiogram to be manipulated and that he believes such manipulation has damaged his ability to demonstrate that his claim was conducted according to "settlement standards."

After reviewing the entire Show Cause record, we find claimant's arguments are without merit. First, claimant does not adequately refute the findings of the auditing cardiologist and the Technical Advisor. Specifically, the auditing cardiologist, Dr. Sorrell, noted that "[t]he color flow traced in the [left atrium] was backflow and not [mitral regurgitation]." Similarly, Dr. Vigilante noted that the RJA measurement on claimant's November 9, 2002 echocardiogram "was diagnostic of backflow." Although Mr. Napora obtained a letter from Dr. Gonzalez after he received the results of Dr. Sorrell's audit, Dr. Gonzalez does not refute the finding of backflow nor does he identify any particular error with Dr. Sorrell's review. Mere disagreement with the auditing cardiologist or Technical Advisor without identifying any specific errors is insufficient to meet a claimant's burden of proof.

We also disagree with claimant that the opinions of Dr. Karalis, Dr. Bauza, or even Dr. Gonzalez establish a reasonable medical basis for his claim. With respect to Dr. Karalis, claimant argues that his opinion undermines the auditing cardiologist's finding of "no regurgitation" and that backflow was included as mitral regurgitation on his study. We disagree. Even if we accept the accuracy of the opinion of Dr. Karalis, he finds only mild mitral regurgitation. He also

explains, "[l]eft [a]trial size and [l]eft [v]entricle size cannot be used to quantify [mitral regurgitation]. However, each of these were [sic] normal, as is the [l]eft [v]entricle function, and the valve appearance, all of which is consistent with a conclusion that Mr. Napora has at most [m]ild [mitral regurgitation]."<sup>8</sup> In addition, contrary to Mr. Napora's representation, Dr. Karalis does not opine that the November 9, 2002 echocardiogram was conducted in accordance with medical standards or that the study did not include backflow. At best, the supplemental declaration is silent on the issue of manipulation. Dr. Bauza determined that Mr. Napora's August 9, 2004 echocardiogram demonstrated only trace mitral regurgitation. In addition, Dr. Gonzalez, following his second review, noted that Mr. Napora's February 23, 2003 echocardiogram demonstrated "[m]ild to borderline moderate mitral insufficiency." As noted above, a claimant is entitled to Level II benefits for damage to the mitral valve only if he or she is diagnosed with moderate or severe mitral regurgitation and one of five complicating factors delineated in the Settlement Agreement. See Settlement Agreement § IV.B.2.c.(2)(b). The opinions of the physicians on whom claimant relies do not establish a reasonable

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8. Claimant objects to the finding of Dr. Karalis that his left atrial dimension was normal because the Trust did not contest Dr. Gonzalez's finding of an abnormal left atrial dimension. Although Dr. Sorrell opined that there was a reasonable medical basis for the finding of an abnormal left atrial dimension, he noted that "[t]he [left atrial] cavity did not exceed the 40/53 [mm] threshold [sic] used for this evaluation, but it was close."

medical basis for Dr. Gonzalez's representation that Mr. Napora had moderate mitral regurgitation.

Further, we are required to apply the standards delineated in the Settlement Agreement and Audit Rules. The context of these two documents leads us to interpret the "reasonable medical basis" standard as more stringent than claimant contends and one that must be applied on a case-by-case basis. As we previously explained in PTO No. 2640, conduct "beyond the bounds of medical reason" can include: (1) failing to review multiple loops and still frames; (2) failing to have a Board Certified Cardiologist properly supervise and interpret the echocardiogram; (3) failing to examine the regurgitant jet throughout a portion of systole; (4) over-manipulating the echocardiogram setting; (5) setting a low Nyquist limit; (6) characterizing "artifacts," "phantom jets," "backflow" and other low velocity flow as mitral regurgitation; (7) failing to take a claimant's medical history; and (8) overtracing the amount of a claimant's regurgitation. See PTO No. 2640 at 9-13, 15, 21-22, 26 (Nov. 14, 2002). Here, Dr. Sorrell and Dr. Vigilante found that Dr. Gonzalez relied upon inaccurate measurements that included backflow, thus artificially overestimating claimant's level of mitral regurgitation. Such an unacceptable practice cannot provide a reasonable medical basis for the resulting diagnosis and Green Form representation that claimant suffered from moderate mitral regurgitation.

Finally, we reject claimant's argument that his claim was prejudiced by the determination that his echocardiogram was manipulated. In fact, in reviewing claimant's November 9, 2002 echocardiogram, Dr. Vigilante specifically stated that he was able to obtain a measurement of claimant's RJA "in spite of increased color gain." In other words, Dr. Vigilante was able to evaluate the level of claimant's mitral regurgitation.

For the foregoing reasons, we conclude that claimant has not met his burden of proving that there is a reasonable medical basis for finding that he had moderate mitral regurgitation. Therefore, we will affirm the Trust's denial of his claim for Matrix Benefits.<sup>9</sup>

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9. Claimant also submitted a letter to the court raising many of these issues anew. In this letter, Mr. Napora sought to have each party who signed a "seventh term sheet" turn over fifty percent of what they received from the Seventh Amendment. He also asked the court to impose a fine and prison time for whomever manipulated his echocardiogram. In addition, he requested an award of \$5,000,000 from both Class Counsel and the Trust "for hiding evidence" of fraud or crimes allegedly committed against him, and he requested \$10,000,000 from Wyeth "for hiding the irregularities of my lawyers [sic] echo[cardiogram] process from me and thus denying my day in court." Finally, he asked that the deadline for requesting additional benefits be extended until 2015. There is no basis in law or fact to grant the relief Mr. Napora seeks. Thus, we will deny his request for relief.